UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,827	05/23/2007	Qainton Van Rooven	44.P001	7183

52418 7590 01/08/2010

HAHN AND MOODLEY, LLP
548 Market Street
San Francisco, CA 94104

EXAMINER	
KENNEDY, NICOLETTA	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
01/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

devasena@hahnmoodley.com
vani@hahnmoodley.com
daya@hahnmoodley.com

Office Action Summary	Application No.	Applicant(s)	
	10/581,827	ROOVEN ET AL.	
	Examiner	Art Unit	
	Nicoletta Kennedy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-13 are currently pending.

Specification

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/IB04/52616, filed 12/1/2004. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where

applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Priority

This application, filed June 2, 2006, is a national state entry of PCT/IB04/52616, filed December 1, 2004, and claims foreign priority to South African application 2003/9481, filed on

December 5, 2003. Applicants have provided a certified copy of the South African application. The instant claims are supported by the South African application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-5, 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Visser et al. (WO 98/56325) (pub. Dec. 17, 1998).

Independent claim 1 claims a transdermal patch with several features:

(a) a selected irritating substance;

(b) a layered construct adapted to be adhered to the skin;

(c) a defining depot cavity between a proximal and distal layer wherein the proximal layer is in contact with skin and is partially permeable and the distal layer is the outer layer and is impervious to the skin; and

(d) a proximal layer that is less permeable to the substance than the skin.

Regarding claims 1 and 4-5, Visser et al. teach a transdermal patch comprising dimethylformamide (DMF), an irritating substance as defined by Applicants in the instant specification (p. 4) (Visser et al., p. 18, lines 17-21). The patient is preferably a human (p. 13, lines 15-19). The patch may comprise a backing (distal) layer and a dermal (proximal) layer that is placed in contact with the skin (p. 18, lines 21-24). The patch comprises DMF, a polar

compound (p. 18, lines 18-19). The backing layer resists chemical attack by the polar compound (p. 18, lines 24-26). The dermal layer is permeable to the polar compound (p. 18, lines 30-32). The polar compound is contained in a reservoir, such as an adsorbant impregnated with the polar compound (p. 18, lines 21-24). Although Visser et al. do not specifically state that the dermal layer is less permeable to the polar compound than is the skin, the same irritating compound, DMF, is used in the examples (p. 21). The dermal layer may be comprised of Teflon™ (p. 18, line 33). However, the reservoir is impregnated with colloidal silicon dioxide (p. 18, lines 29-30). Applicants teach in the instant specification (p. 10) and in claim 5 that a silicone material has a lesser rate of permeability than does the skin. Therefore, Visser et al. anticipate instant claims 1 and 4-5.

Regarding claim 7, Visser et al. teach that the patch may take the form of a disk and may be self-adhesive (p. 19, line 1 and 11). Therefore, Visser et al. anticipate instant claim 7.

Regarding claim 10, Visser et al. teach that colloidal silicone dioxide is impregnated with DMF (p. 26).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. **Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) in view of Landauer et al. (WO 99/13885) (pub. Mar. 25, 1999).**

Regarding claim 1, Visser et al. teach a transdermal patch comprising dimethylformamide (DMF), an irritating substance as defined by Applicants in the instant specification (p. 4) (Visser et al., p. 18, lines 17-21). The patient is preferably a human (p. 13, lines 15-19). The patch may comprise a backing (distal) layer and a dermal (proximal) layer that is placed in contact with the skin (p. 18, lines 21-24). The patch comprises DMF, a polar compound (p. 18, lines 18-19). The backing layer resists chemical attack by the polar compound (p. 18, lines 24-26). The dermal layer is permeable to the polar compound (p. 18, lines 30-32). The polar compound is contained in a reservoir, such as an adsorbant impregnated with the polar

compound (p. 18, lines 21-24). Although Visser et al. do not specifically state that the dermal layer is less permeable to the polar compound than is the skin, the same irritating compound, DMF, is used in the examples (p. 21). The dermal layer may be comprised of Teflon™ (p. 18, line 33). However, the reservoir is impregnated with colloidal silicon dioxide (p. 18, lines 29-30). Applicants teach in the instant specification (p. 10) and in claim 5 that a silicone material has a lesser rate of permeability than does the skin.

However, Visser et al. fail to teach that the proximal and distal layers are the same or the rate of permeability of DMF through the patch. Landauer et al. cure this deficiency.

Regarding claims 2-3, Landauer et al. teach the transdermal administration of DMF to a patient (p. 13). The patch is comprised of high density nylon backing material and a low density nylon (p. 15). The patch further comprises a hydrophobic or hydrophilic nylon or PTFE membrane (p. 15).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Visser et al. with those of Landauer et al. to vary the density of the proximal and distal layers to result in flow of the drug through the proximal layer to the patient's skin. One would have been motivated to do so because this simplifies the design of the patch while allowing control over the flux of the drug.

Regarding claim 6, Landauer et al. teach that the tempo of drug administration is determined by the skin and thus the desorption of the drug through the membrane should be the same or very close to the absorption tempo of the skin (p. 14). Therefore, if the desorption of the drug through the membrane is the same as the absorption tempo of the skin, excess build-up of DMF on the skin of the patient is avoided.

Regarding claim 8, Landauer et al. and Visser et al. each teach the use of silicon dioxide (diactomaceous earth) in the patch (Landauer et al. p. 17, Visser et al. p. 26).

Regarding claim 9, Visser et al. teach that DMF is absorbed through the skin at 9.4 $mg/cm^2/hr$ (p. 27). Landauer et al. teach that the tempo of drug administration is determined by the skin and thus the desorption of the drug through the membrane should be the same or very close to the absorption tempo of the skin (p. 14). Therefore, Landauer et al. teach that the patch may have a permeability of about 9.4 $mg/cm^2/hr$. MPEP 2144.05 states that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties" (quoting *Titanium Metals Corp. of America v. Banner,* 778 F.2d 775, 227 USPQ 774 (Fed. Cir. 1985)). In the instant case, about 9.4 $mg/cm^2/hr$ is so close to 9 $mg/cm^2/hr$ that the patch is expected to have the same permeability properties and reduction in buildup of DMF on the skin of the patient.

Regarding claim 11, Landauer et al. teach that indirect administration of DMF may be done by introducing a known amount of DMF with a syringe into the silicon dioxide adsorbent after the patch has been applied to the skin (p. 17).

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) and Landauer et al. (WO 99/13885) (pub. Mar. 25, 1999) as applied to claims 1-11 above, and further in view of Reed (US 5,827,530) (pub. Oct. 27, 1998).

The combination of Visser et al. and Landauer et al. teach each aspect of claim 11. While they teach that DMF may be injected into the patch after the patch has been applied to the

patient, they fail to teach that there is a self-reclosing nipple or port formation. Reed cures this deficiency.

Regarding claim 12, Reed teaches a fillable transdermal delivery device that utilizes injection ports for post assembly introduction of medicinally active agents (abstract).The fillable reservoir of the transdermal device is filled by means of loading a needle with the active agent and inserting the needle through the septum of the loading port (abstract).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Visser et al. and Landauer et al. with those of Reed. to use an injection port for injecting DMF into the patch reservoir. One would have been motivated to do so because this allows the person injecting the DMF to inject the DMF into the reservoir and not into another part of the patch. Further, Reed provide a shield in the interior of the fillable reservoir to protect the diffusion membrane from damage in the event that the needle is inserted too far (abstract).

6. **Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) and Landauer et al. (WO 99/13885) (pub. Mar. 25, 1999) as applied to claims 1-11 above, and further in view of Ebert et al. (WO 95/25172) (pub. Sept. 14, 1995).**

Visser et al. teach that the patch may be self adhesive but fail to teach that the patch and proximal layer are covered by a peelable cover layer. Ebert et al. cure this deficiency.

Ebert et al. teach a method for making a transdermal drug delivery device comprising a proximal peelable film and an adhesive layer (claim 21).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Visser et al. with those of Ebert et al. to cover the proximal layer and adhesive with a removable peelable layer. One would have been motivated to do so because Visser et al. teach a self-adhesive patch with a proximal layer and suggest sealing the patch for storage. Ebert et al. teach a specific method of sealing: using a removable peelable layer, similar to how the adhesive and gauze of a band-aid are protected prior to use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./
Examiner, Art Unit 1611

/David J Blanchard/
Primary Examiner, Art Unit 1643